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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

PHAM, HAI CHI

ART UNIT

PAPER NUMBER

2861

DATE MAILED: 07/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/875,660

Applicant(s)

LAMBERT ET AL.

Examiner

Hai C Pham

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 31-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 31-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-2, 5-7, 9-14, 16-21, 31-32, 34-39, 42 are rejected under 35 U.S.C. 102(b) as being anticipated by the Annual Book of ASTM Standards (published in 1996).

The "Standard Practice for Use of Calorimetric Dosimetry Systems for Electron Beam Dose Measurements and Dosimeter Calibrations", the non-patent literature document submitted as prior art by Applicants, discloses all the basic limitations of the claimed invention, namely a calorimetric dosimetry system and method for routine calibration and radiation dosage measurement of electron beam radiation source intended for radiation processing applications, the system/method including:

- a radiation source (electron beam radiation source) which is configured to emit a radiation dose, a calorimeter (graphite calorimeter) which is configured to be irradiated by said source with a dose of radiation, a calorimeter controller (not shown) for determining the radiation dosage given to the calorimeter from the difference between the temperature of the calorimeter before (paragraph 8.1.1) and after the irradiation of the calorimeter (paragraph 8.1.5), the temperature

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difference being a function of the radiation dose received from the radiation source (see section 8, at page 4),

- a conveyor system which is configured to receive the medical product and the calorimeter and to convey the product and the calorimeter to the radiation source (paragraph 8.1),
- providing a calorimeter control system and a validated thermistor calorimeter having a validated resistance-temperature calibration relationship and a validated temperature-dosage calibration relationship (paragraph 7.2.2), measuring an initial calorimeter temperature (T_1), irradiating the calorimeter with a dose of radiation from a radiation source, measuring a subsequent calorimeter temperature before significant heat loss has occurred (T_2) (paragraphs 8.1.1 to 8.1.5), determining the radiation dose (D_M) using a calculated temperature difference between said initial temperature and subsequent temperature measurements, and using said resistance-temperature and said temperature-dosage calibration relationships (paragraph 8.1.9), repeating the preceding steps at an interval determined by said calorimeter controller, irradiating said medical product with a dose of radiation from the radiation source (paragraphs 8.3.4 to 8.3.5), and reporting said determined radiation dose,
- the controlled radiation source comprises a high dose-rate source (electron beams in the energy range from 4 to 12 MeV) (paragraph 1.2),
- the high dose-rate radiation source is an electron radiation source effective to provide a dose of electron beams radiation (paragraph 1.2),

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- the step of measuring a subsequent calorimeter temperature occurs within about 30 minutes after irradiating the calorimeter (see Fig. 3),
- the step of measuring a subsequent calorimeter temperature occurs within about 15 minutes after irradiating the calorimeter (see Fig. 3),
- the radiation dose is between about 0.1 kGy to about 100 kGy, or between about 2 kGy to about 70 kGy, or between about 3 kGy to about 40 kGy (the radiation dose range shown at paragraph 1.3 is well within the claimed ranges),
- the calorimeter is a thermistor calorimeter (paragraph 6.1) and said measuring steps comprise a step of contacting said thermistor calorimeter with a resistance measuring device (high-precision ohm-meter) (paragraph 6.6.1).

The above non-patent literature document discloses using the calorimeter for calibrating dosimeter system in electron beams intended for radiation processing applications (paragraph 1.1) but does not expressly indicate a sterilization system for a medical product. Regardless, the intended use recitation of the sterilization system for a medical product in which a calorimeter is used to monitor the radiation dose, does not result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 3-4, 41, 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Annual Book of ASTM Standards in view of Gschneidner, Jr. et al. (U.S. 5,806,979).

The Annual Book of ASTM Standards discloses all the basic limitations of the claimed invention except for the computer-controlled automatic controller, and the recalibration routine.

Gschneidner, Jr. et al. discloses a calorimetric system and method for monitoring a calorimeter temperature by reading the resistance of a thin film resistor (sensor 24) over a specified temperature interval, the calorimeter temperature monitor being performed automatically by a data collection software (col. 7, lines 1-55).

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to incorporate the data collection software as taught by Gschneidner, Jr. et al. into the method listed in the Annual Book of ASTM Standards. The motivation for doing so would have been to allow a precise determination of the temperature difference as well as accurate measurement of the radiation dose to be performed.

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5. Claims 8, 15, 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Annual Book of ASTM Standards in view of Douglas-Hamilton et al. (U.S. 4,812,663).

The Annual Book of ASTM Standards discloses all the basic limitations of the claimed invention except for the conveyor having a close-loop route.

Douglas-Hamilton et al. discloses a calorimetric does monitor for ion implantation equipment, where the determination of the radiation dosage is based on the difference of temperature of the calorimeter before and after the irradiation of the calorimeter, the temperature difference is function of the radiation dosage received from the radiation source, and wherein the calorimeter controller controls the time interval between emitting a radiation dose from the radiation source and measuring the temperature of the calorimeter (the determination of the temperature being determined as a function of time) (col. 2, lines 16-24). Douglas-Hamilton et al. further teaches a disk conveyor system (11) for receiving the workpiece (12).

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to incorporate the close-loop route conveyor as taught by Douglas-Hamilton et al. into the device disclosed in the Annual Book of ASTM Standards. The motivation for doing so would have been to allow a series of the radiation dosage measurements to be performed to provide accurate results.

6. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over the Annual Book of ASTM Standards in view of Sliiski et al. (U.S. 5,635,709).

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The Annual Book of ASTM Standards discloses all the basic limitations of the claimed invention except for the robotic arm.

Sliski et al. discloses a method and apparatus for measuring radiation dose distribution, the apparatus including a radiation sensor for measuring the radiation dose and a positioning system for moving the probe with respect to the radiation sensor. The positioning system also orients the sensor for optimal dose measurements and is provided with a robotic arm.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to incorporate a robotic arm as taught by Sliski et al. in the device of the Annual Book of ASTM Standards for the purpose of handling hazardous material during the measurement of the radiation dose.

Response to Arguments

7. Applicant's arguments with respect to claims 1-21, 31-44 have been considered but are moot in view of the new grounds of rejection presented in this office action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hai C Pham whose telephone number is (703) 308-1281. The examiner can normally be reached on T-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Benjamin R. Fuller can be reached on (703) 308-0079. The fax phone

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numbers for the organization where this application or proceeding is assigned are (703) 308-7722, (703) 308-7724, (703) 308-7382, (703) 305-3431, (703) 305-3432 for regular communications and Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0956.



HAI PHAM
PRIMARY EXAMINER

July 10, 2003